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2. Patent application number
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3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ADVANCED MEDICAL DIAGNOSTICS GROUP LIMITED
4 EDMUND COURT, BEACONSFIELD
BUCKINGHAMSHIRE HP9 1YT
UNITED KINGDOM

08600074001
Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation — ENGLAND

4. Title of the invention

APPARATUS FOR PROCESSING AN ECG SIGNAL

5. Name of your agent *(if you have one)*

URQUHART-DYKES & LORD

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

TOWER HOUSE
MERRION WAY
LEEDS LS2 8PA

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Apparatus for processing an ECG signal

The present invention relates to an apparatus for processing an ECG signal.

Cardiac monitors have been used for some time to measure electrocardiographs of a subject to determine whether their heart is in good physical condition. One set of parameters which is often looked at is the QRS component of the PQRST complex which occurs during each successive heartbeat. The temporal separation between the R peak associated with consecutive heartbeats is of particular interest to medical practitioners. The rate at which the R wave peak appears and variations in the amplitude of those peaks give an indication as to the strength and health of the heart, in particular the functioning of the autonomic nervous system.

Existing monitors incorporate a transmitter which is placed directly onto the subject and has a pair of electrodes which record an electrocardiograph or ECG. The time interval between successive R wave peaks in the subjects ECG are evaluated directly in the transmitter and then transmitted as a string of numerical values by telemetry to a remote receiver where the results can be stored and analysed. However, such systems lack the capability to transmit the original ECG which is also of use to medical practitioners. Viewing the accumulated R-R interval values and the corresponding ECG simultaneously enables a medical practitioner to spot tachycardia, ectopic beats or other cardiac irregularities. If the quality of the data in the ECG appears to be poor the practitioner can simply reject the recorded data and begin again.

Other known monitors transmit a recorded ECG either digitally or by analogue means to a remote receiver. The R-R intervals are then evaluated on the receiver side, frequently in a PC, where the results can be stored and analysed. These systems have the disadvantage that a relatively wide radio channel is required to transfer the entire ECG at a minimum sampling rate of 1000 Hz, which is required to meet an acceptable R-R interval measuring precision of 1ms. To transmit the entire ECG signal at such a sampling rate requires a relatively wideband telemetry channel. The wider a channel is the more sensitive it is to radio interference which can introduce errors into the R-R values calculated in the receiver. Wideband transmission also involves a high power consumption and is relatively expensive.

According to a first aspect of the present invention there is provided apparatus for processing an ECG signal, the apparatus comprising:

a transmitter having an input for receiving the signal and a processor which separates the signal into first and second signal components, manipulates the first signal component to determine the temporal spacing between consecutive R-peaks in the QRS complex of the signal, and in which the second signal component consists of the ECG signal; and

a receiver;

in which the transmitter transmits both the manipulated first signal component and the second signal component to the receiver.

By transmitting both the temporal spacings between consecutive R peaks, or R-R interval values, and the original ECG signal a medical practitioner has much more information than previously available using other devices. The R-R interval values can be analysed to check on the health of the heart and many other autonomic functions of the body. Moreover, the ECG itself can be viewed simply to check that there are no irregularities occurring in the ECG signal. If the data in an ECG trace appears corrupted an operator can simply stop recording.

Figure 6A shows the characteristic wave peaks and troughs of a PQRST complex (labelled P, Q, R, S, and T) which are present in a raw ECG signal. Figures 6B and 7 illustrate the result of differentiating the raw ECG signal to determine the occurrence of the R peak for a given PQRST complex. In Figures 6B and 7, Q', R', and S' represent the turning points or first moments associated with the Q, R, and S peaks respectively. Figures 6B and 7 show only the QRS portion of the PQRST complex as the P and T waves are suppressed by a differentiating circuit (details of which will follow later) which operates on the ECG signal to determine the first derivative or first moment.

In Figure 7 the time and voltage scales have been magnified for clarity. The y-ordinate which does not represent millivolts but a numeric value resulting from A/D conversion (details of which follow later). A nominal zero level of 128 has been adopted with values between 0 and 127 (inclusive) designated as negative and those between 129 and 255 (inclusive) designated as positive. The signal shown in Figure 6B no longer represents genuine Q, R and S waves due to the effects of a first signal filter (details of which follow later). However, this change of shape does not ultimately affect the measurement of R-R time intervals.

The important features which can be obtained from the differentiated signal shown in Figures 6B and 7 are:

1) the downward zero crossing corresponding to the R wave peak which can be used as a precise fiducial point (shown as R'or T_{down}); and

2) the amplitude of the waveform which is directly proportional to that of the original QRS complex, thus enabling it to be used for accurate R peak identification.

Known methods of R peak identification generally involve simply comparing the amplitude of a raw ECG signal against a fixed or a varying threshold value. If the amplitude is greater than or equal to the fixed value or the varied value a peak is accepted as an R peak. However, if a monitor is incorrectly positioned or if the subject is moving around the R peak may not necessarily be the feature in a given PQRST complex which has the greatest amplitude. In particular, if a subject is exercising the signal may be very noisy and the amplitude of successive R peaks may vary quite considerably.

A method and system of identifying R peaks is disclosed in a co-pending UK patent application entitled "Method and apparatus for identifying features in an ECG signal" filed 28 March 2003 under agents reference RSF/P204096 (which is incorporated herein by reference). This method and system utilise the following points of interest in a differentiated ECG signal as illustrated in Figure 7:

1) the temporal position of the maximum amplitude, associated with the maximal positive ECG slope (T_{max});
2) the temporal position of a turning point associated with an R peak (T_{down});
3) the maximum amplitude (MAX); and
4) the minimum amplitude, associated with maximal negative ECG slope (MIN).

The difference is calculated between the maximum amplitude and the minimum amplitude and the result compared with a predetermined amplitude value. The temporal occurrence of the maximum (T_{max}) is measured relative to a predetermined temporal reference point. A temporal difference is also calculated between the time of occurrence of the turning point (T_{down}) and the maximum (T_{max}) and the result is compared to a predetermined time value. If both the amplitude difference and the temporal difference are greater than or equal to the predetermined amplitude value and predetermined time value respectively the temporal occurrence of the turning point is identified as that of a potential R peak.

Preferably, the processor comprises an amplifier which amplifies the ECG signal prior to separation into first and second signal components. This strengthens the signal before further processing. In certain embodiments a differential amplifier may be used.

Conveniently, the processor further comprises first and second signal filters which separate the electrocardiograph signal into the first and second signal components.

Preferably, the first signal filter includes a first high-pass filter. In other embodiments, the second signal filter includes a second high-pass filter. The high-pass filter(s) may remove signal components having a frequency lower than 50 Hz. Most preferably, the high-pass filter(s) removes signal components having a frequency lower than approximately 34 Hz. Use of a high-pass filter removes undesirable signals, such as cardiac artefacts, prior to A/D conversion of the signal.

In preferred embodiments, the output from the first and/or second high-pass filter is fed into a low-pass filter. Low-pass filters eliminate noise and radio frequency signals which may be greater than the ECG signal spectrum. Conveniently, the low-pass filter includes an operational amplifier. Use of filters which include operational amplifiers suppress noise and radio frequency signals present in the first and/or second signal components.

Conveniently, the processor includes a micro-controller which receives the first and second signal components and converts at least the first signal component to a digital signal prior to manipulation to determine the R-R time intervals.

Preferably, the first and second signal components are fed into a data stream for transmission to the receiver.

Preferably, the processor includes a micro-controller which receives the first and second signal components, converts the two components from analogue signals to digital signals for transmission to the receiver. Conveniently, the digitised first and second components are fed into a data stream for transmission to the receiver. Signals transmitted digitally are less prone to data loss or interference than analogue signals.

Conveniently, the processor samples the first signal component between 500 Hz and 2000 Hz. Most preferably, the processor samples the first signal component at approximately 1000Hz.

Conveniently, the processor samples the second signal component at approximately 500 Hz. The second signal component may be sampled between 120 and 500 Hz. In certain embodiments, the second signal component may be sampled between 120 to 150 Hz.

The second signal component comprises a signal which is indicative of the measured ECG. As the ECG in the second signal component is required only for visual purposes, the entire ECG need not be transmitted. Reducing the amount of data which needs to be transmitted reduces the transmission bandwidth required. Thus, no wideband telemetry channel is required to transmit the measured ECG signal. Narrowband radio channels are less sensitive to radio interference, have lower power consumption and are generally cheaper to operate. The apparatus uses a relatively high sampling rate for the evaluation of the R-R intervals directly in the transmitter. This gives the required accuracy for determining the temporal spacings between the consecutive R-R peaks. Sampling the first signal component at a rate of around 1000 Hz allows the first signal component to be manipulated to create a string of R-R intervals at the required accuracy i.e. of around 1ms.

According to a further aspect of the invention there is provided a method for processing an ECG signal, the method comprising the steps of:

receiving the signal at an input of a transmitter, the transmitter having a processor which separates the signal into first and second signal components, and manipulates the first signal component to determine the temporal spacing between consecutive R-peaks in the QRS complex of the signal, and in which the second signal component consists of the ECG signal; and

transmitting both the manipulated first signal component and the second signal component to a receiver.

By transmitting both the temporal spacings between consecutive R peaks, or R-R interval values, and the original ECG signal a medical practitioner has much more information than previously available using other devices. The R-R interval values can be analysed to check on the health of the heart and many other autonomic functions of the body. Moreover, the ECG itself can be viewed simply to check that there are no irregularities occurring in the ECG signal. If the data in an ECG trace appears corrupted an operator can simply stop recording.

Preferably, the method further comprises the step of amplifying the ECG signal prior to separation into first and second signal components. This strengthens the signal before further processing. In certain embodiments a differential amplifier may be used.

Conveniently, the method further comprises the step of separating the ECG signal into the first and second signal components using first and second signal filters.

In preferred embodiments, the method includes the step of filtering the first signal component using a high-pass filter.

Conveniently, the method comprises the step of feeding the output from the high-pass filter into a low-pass filter.

Preferably, the method comprises the steps of:

providing a micro-controller in the processor ;

receiving the first and second signal components in the micro-controller; and

converting at least the first signal component to a digital signal prior to manipulation to determine the R-R time intervals.

In preferred embodiments, the method comprises the step of feeding the first and second signal components into a data stream for transmission to the receiver.

Preferably, the method comprises the step of sampling first signal component between 500 Hz and 2000 Hz.

Conveniently, the method comprises the step of sampling the first signal component at approximately 1000Hz.

In preferred embodiments, the method comprises the step of sampling the second signal component at approximately 500 Hz.

An embodiment of the present invention will now be described, by way of example only, with reference to the following drawings in which:

Figure 1 is a schematic illustrating how a transmitter of an ECG monitor, in accordance with the present invention, operates;

Figure 2 is a schematic illustrating how a receiver associated with the transmitter in Figure 1 operates;

Figure 3 shows a circuit diagram of the transmitter of Figure 1;

Figure 4 shows a circuit diagram of the receiver of Figure 2;

Figure 5 is a schematic illustrating the operation a diversity reception circuit in the receiver of Figures 2 and 4;

Figure 6A shows an amplified PQRST complex for a single heartbeat as measured in an ECG;

Figure 6B shows the result of differentiating the signal in Figure 6A; and

Figure 7 shows a more detailed view of the differentiated signal of Figure 6B.

The apparatus of the present invention is shown schematically in Figures 1 and 2. Figure 1 shows a transmitter 10 which can be placed on a subjects body to record a cardiac signal. The transmitter 10 may be attached to a belt (not shown) and worn around the subjects chest. The transmitter 10 has two electrodes 12 which can be attached to the subjects body to record an electrocardiograph or ECG. The signal is dealt with by a processor (details of which will follow) which includes first and second signal filters 14, 16 and a micro-controller 18.

The recorded signal passes to the first and second signal filters 14, 16 which separate the signal into first and second signal components. The first signal component is then manipulated by the processor to evaluate the temporal spacing between consecutive R wave peaks in the QRS complex of the electrocardiograph signal. The first and second signal components are then fed into the micro-controller 18 where the sampling rate of the second component, which effectively consists of the raw ECG, is reduced. The micro-controller 18 feeds the first signal component and reduced sampling rate second signal component into a digitised data stream and on to a radio transmitting module 20 for telemetric transmission from a transmission antenna 22.

The operation of the transmitter will now be described in greater detail with reference to Figure 3. An ECG signal is recorded by means of a pair of electrodes 12 which can be placed in contact

with the skin of a subject. The recorded ECG signal initially passes through a pair of low-pass RC filter circuits 100, 102 which consist of a resistor R3 and a capacitor C1, and a resistor R4 and a capacitor C2, respectively. In the present embodiment, resistors R3 and R4 are set to 10 K ohm and capacitors C1 and C2 are set to 100 pF. The outputs from the filter circuits 100, 102 form the inputs to a differential amplifier 104 based on an AD 627 integrated circuit. The low-pass filter circuits 100, 102 filter high frequency signals which result from radio module operation and protect the amplifier inputs against damage by high level impulse over-voltage (electrostatic discharge voltage).The differential amplifier 104 differentiates the signal from background noise to create a relatively "clean" signal.

Two resistors R1 and R2 (101, 103) serve as a DC bias supply which is necessary for proper functioning of the differential amplifier 104. The values of the resistors R1 and R2 (101, 103) are selected to provide a high impedance to the differential amplifier inputs. In the present embodiment, resistors R1 and R2 are set to 8 M ohm. A DC bias is created by a resistor divider R21, R26 (105) and blocked by a capacitor C14. The gain of the differential amplifier 104 is set by a further resistor R5 (106). In the present embodiment, resistors R21, R26 and R5 are respectively set to 4 K ohm, 4 K ohm, and 12 K ohm and capacitor C14 set to 220 nF. The gain of the differential amplifier 104 is selected to prevent saturation from any ECG signal baseline drift.

After basic amplification by the differential amplifier 104 the rough ECG signal 107 is divided into two signal components by the first and second signal filters 14, 16 which adjust the signal spectra and provide sufficient amplification necessary for the channels of an A/D converter which is integrated on the same silicon chip as the micro-controller 18. The first and second signal components are fed into a pair of high-pass filter circuits 108, 111. The first of these high-pass filter circuits 108 includes a resistor R12 and a capacitor C5 the values of which are set such that the circuit 108 differentiates the signal. The second high-pass filter circuit 111 also has a resistor R11 and a capacitor C4 but does not differentiate the signal. In the present embodiment, resistors R12 and R11 are set to 100 K ohm and 1 M ohm respectively, and capacitors C5 and C4 set to 47 nF and 220 nF respectively.

From signal theory it is known that only the QRS complex of the ECG signal need be considered to obtain precisely measured R-R intervals. The frequency spectrum of the QRS complex contains frequencies in the range of around 20 to 100 Hz. Undesirable signals such as cardiac artefacts have

a 1/f-type spectrum with their main components being located below 20 Hz. It is therefore useful to process the rough ECG signal using a high-pass filter 108 before A/D conversion. In practice a cut-off frequency of around 34 Hz is used.

Filtering and amplifying of the first and second signal components 109, 112 of the ECG signal are performed by OP 295 single-supply micro-power operating amplifiers 110, 113 with "rail-to-rail" capability. These operational amplifiers 110, 113 allow the A/D converter reference voltage to be used as an operating amplifier power supply with no loss in A/D converter input range. Both signal branches 114, 116 act as an low-pass filters, the cut-off frequencies determined by resistor R10 and capacitor C3, and resistor R15 and capacitor C6, respectively. In the present embodiment, resistors R10 and R15 are set to 100 K ohm and capacitors C3 and C6 are set to 2.2 nF. These low pass filters eliminate noise and radio frequency signals which are greater than the ECG signal spectrum. Resistors R8 and R13 determine the first and second channel gain for the signal branches. Resistors R9 and R14 are used for the differential amplifier 104 input bias current compensation and to avoid unwanted DC level shift in output signal. In the present embodiment, resistors R8, R13, R9 and R14 are respectively set to 3 K ohm, 1 K ohm, 1 M ohm, and 100 K ohm.

The overall operations of the transmitter 10 are controlled by a micro-controller 18. In the described embodiment a PIC16C711 micro-controller is used (manufactured by Microchip). This is a low power device is based on "Dual Bus Harvard RISC" architecture and provides high computational power relative to its power consumption. The micro-controller 18 has four integrated A/D converter channels, only three of which are used, which allow direct connection to the first and second signal filters 14, 16 and thus significantly reduce the complexity of the transmitter circuitry. The main functions performed by the micro-controller 18 are sampling and A/D conversion of the ECG signal from both signal branches.

The sampling rate for the first signal component 109 of the ECG signal is around 1000 Hz. This corresponds to a time interval of around 1 ms which is necessary to obtained accurate R-R intervals from the ECG signal. The sampling rate for the second component 112 may be set at somewhere between 100 and 500 Hz.

Further functions performed by the micro-controller 18 include coding of measured R-R interval values (first signal component), ECG signal samples (second signal component) and battery status

into a serial data stream using a dedicated transfer protocol prior to telemetric transfer, charging control of internal lithium-ion rechargeable battery (two-stage CC and CV charging method), diagnostics and service functions.

As described above, the recorded ECG signal is amplified and digitally processed directly in the transmitter 10 (on the patient's body) and an instantaneous heart rate (R-R intervals) precisely derived. This information together with the raw ECG signal and battery status information are encoded by a transfer protocol into a serial code (suitable for optimal narrowband radio channel exploitation) and transmitted in the UHF band by the radio transmitting module 20 and transmission ariel 22. The transmitted signal is in digital form.

Referring now to Figures 2 to 5, the present invention incorporates a technique known as diversity reception which eliminates fading of a transmitted signal. Fading is caused by multipath wave propagation, which results from reflection and absorption of transmitted radio waves between a transmitter and a receiver. Multiple waves received by an ariel will be added together according to the principle of vector summation. This means that in certain conditions (when the waves are in opposite phase) the vector sum may be close to zero and transferred information may be lost.

An effective way of overcoming this problem is to use two spaced apart antennae 32, 34 which increases the probability of a good signal level being received in one antenna if the signal received in the other antenna suffers interference. Summing signals from the two antennae is likely to encounter the problem of out of phase signals cancelling each other out. The signals received by the two receiver antennae 32, 34 are switched by the analogue switching circuit which determines the best quality signal. The selected signal is processed in a data recovery circuit (slicer) which separates the digital data from analog signal.

The transmitted signal is received by one or both of a pair of receiver antennae 32, 34 which form part of a remote receiver 30. The receiver antennae 32, 34 operate under diversity reception to ensure that the best quality signal available is received by the receiver 30. The received signal (s) pass through a pair of receiver module 36, 38 which pass the signal(s) to a receiver micro-controller 44 either directly or via an analogue switch 40 and a data recovery unit 42. Data processed by the micro-controller 44 by a suitable connector 46 to and from a PC. In the described embodiment the connector 46 is an RS232-type interface.

Claims:

1. Apparatus for processing an ECG signal, the apparatus comprising:

a transmitter having an input for receiving the signal and a processor which separates the signal into first and second signal components, manipulates the first signal component to determine the temporal spacing between consecutive R-peaks in the QRS complex of the signal, and in which the second signal component consists of the ECG signal; and

a receiver;

in which the transmitter transmits both the manipulated first signal component and the second signal component to the receiver.

2. Apparatus as claimed in claim 2 in which the processor comprises an amplifier which amplifies the ECG signal prior to separation into first and second signal components.

3. Apparatus as claimed in claim 1 or claim 2 in which the processor further comprises first and second signal filters which separate the electrocardiograph signal into the first and second signal components.

4. Apparatus as claimed in claim 3 in which the first signal filter includes a high-pass filter.

5. Apparatus as claimed in claim 4 in which the output from the high-pass filter is fed into a low-pass filter.

6. Apparatus as claimed in any preceding claim in which the processor includes a micro-controller which receives the first and second signal components and converts at least the first signal component to a digital signal prior to manipulation to determine the R-R time intervals.

7. Apparatus as claimed in any preceding claim in which the first and second signal components are fed into a data stream for transmission to the receiver.

8. Apparatus as claimed in any preceding claim in which the processor samples the first signal component between 500 Hz and 2000 Hz.

9. Apparatus as claimed in any preceding claim in which the processor samples the first signal component at approximately 1000Hz.

10. Apparatus as claimed in any preceding claim in which the processor samples the second signal component at approximately 500 Hz.

11. A method for processing an ECG signal, the method comprising the steps of:

receiving the signal at an input of a transmitter, the transmitter having a processor which separates the signal into first and second signal components, and manipulates the first signal component to determine the temporal spacing between consecutive R-peaks in the QRS complex of the signal, and in which the second signal component consists of the ECG signal; and

transmitting both the manipulated first signal component and the second signal component to a receiver.

12. A method as claimed in claim 11 further comprising the step of amplifying the ECG signal prior to separation into first and second signal components.

13. A method as claimed in claim 11 or claim 12 further comprising the step of separating the ECG signal into the first and second signal components using first and second signal filters.

14. A method as claimed in claim 13 which includes the step of filtering the first signal component using a high-pass filter.

15. A method as claimed in claim 14 comprising the step of feeding the output from the high-pass filter into a low-pass filter.

16. A method as claimed in any preceding claim comprising the steps of:

providing a micro-controller in the processor ;

receiving the first and second signal components in the micro-controller; and

converting at least the first signal component to a digital signal prior to manipulation to determine the R-R time intervals.

17. A method as claimed in any preceding claim comprising the step of feeding the first and second signal components into a data stream for transmission to the receiver.

18. Apparatus as claimed in any preceding claim comprising the step of sampling first signal component between 500 Hz and 2000 Hz.

19. Apparatus as claimed in any preceding claim comprising the step of sampling the first signal component at approximately 1000Hz.

20. A method as claimed in any preceding claim comprising the step of sampling the second signal component at approximately 500 Hz.

21. Apparatus as described hereinbefore with reference to the accompanying drawings.

22. A method as described hereinbefore with reference to the accompanying drawings.

Abstract

Apparatus for processing an ECG signal

Apparatus for processing an ECG signal has a transmitter 10 with an input 12 for receiving the signal. The transmitter 10 also has a processor 14, 16, 18 which separates the signal into first and second signal components and manipulates the first signal component to determine the temporal spacing between consecutive R-peaks in the QRS complex of the signal. The second signal component consists of the ECG signal itself. The apparatus also includes a receiver (not shown), to which the transmitter 10 transmits both the manipulated first signal component and the second signal component.

[Figure 1]

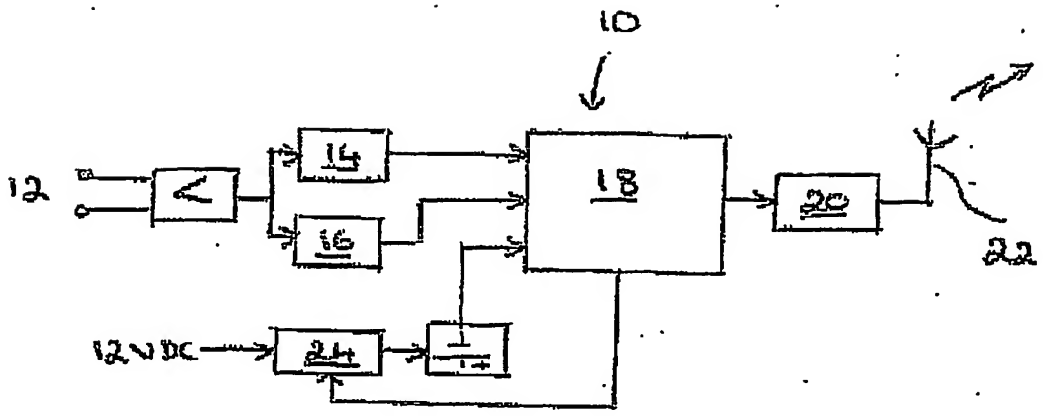

FIGURE 1

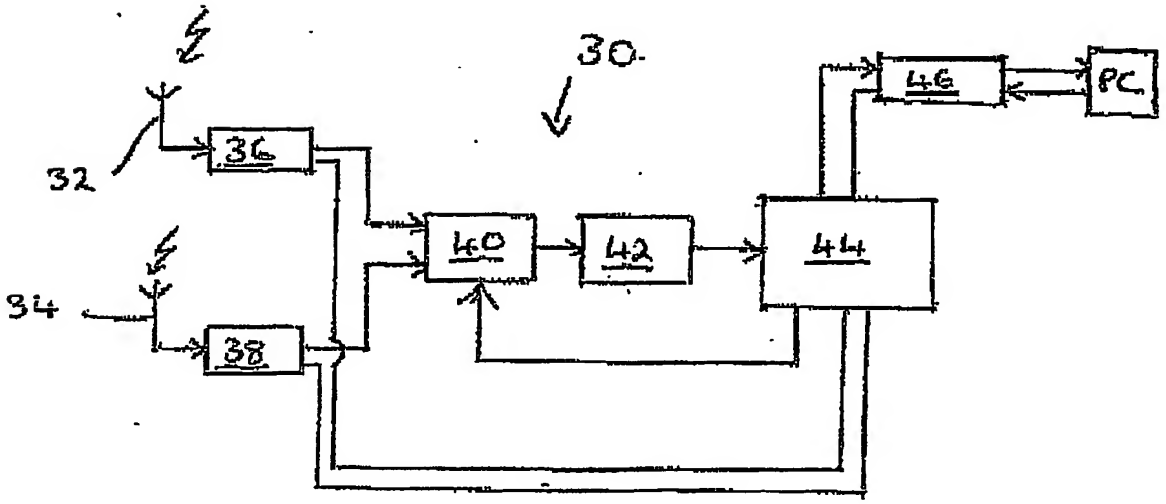

FIGURE 2

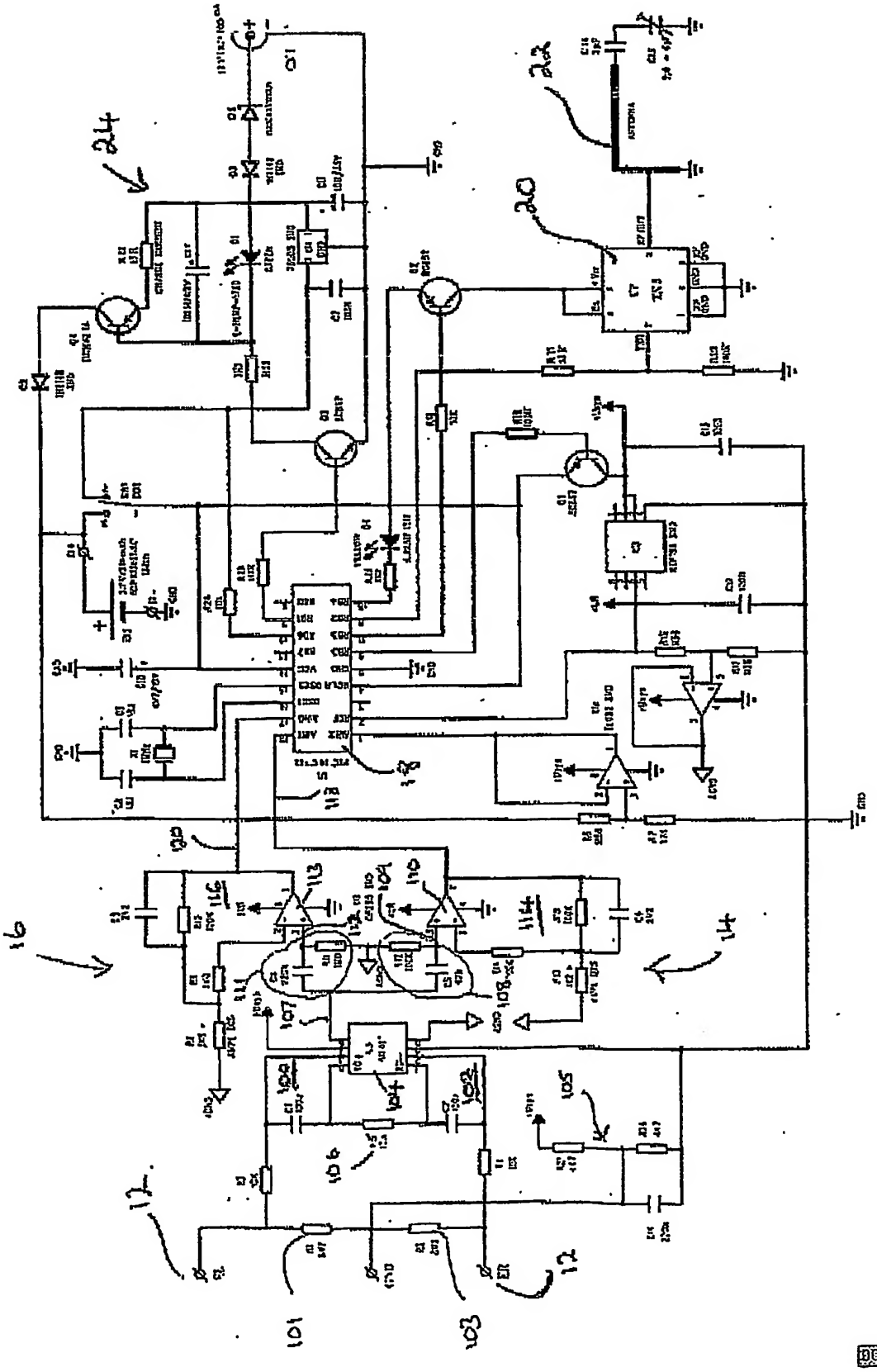

FIGURE 3

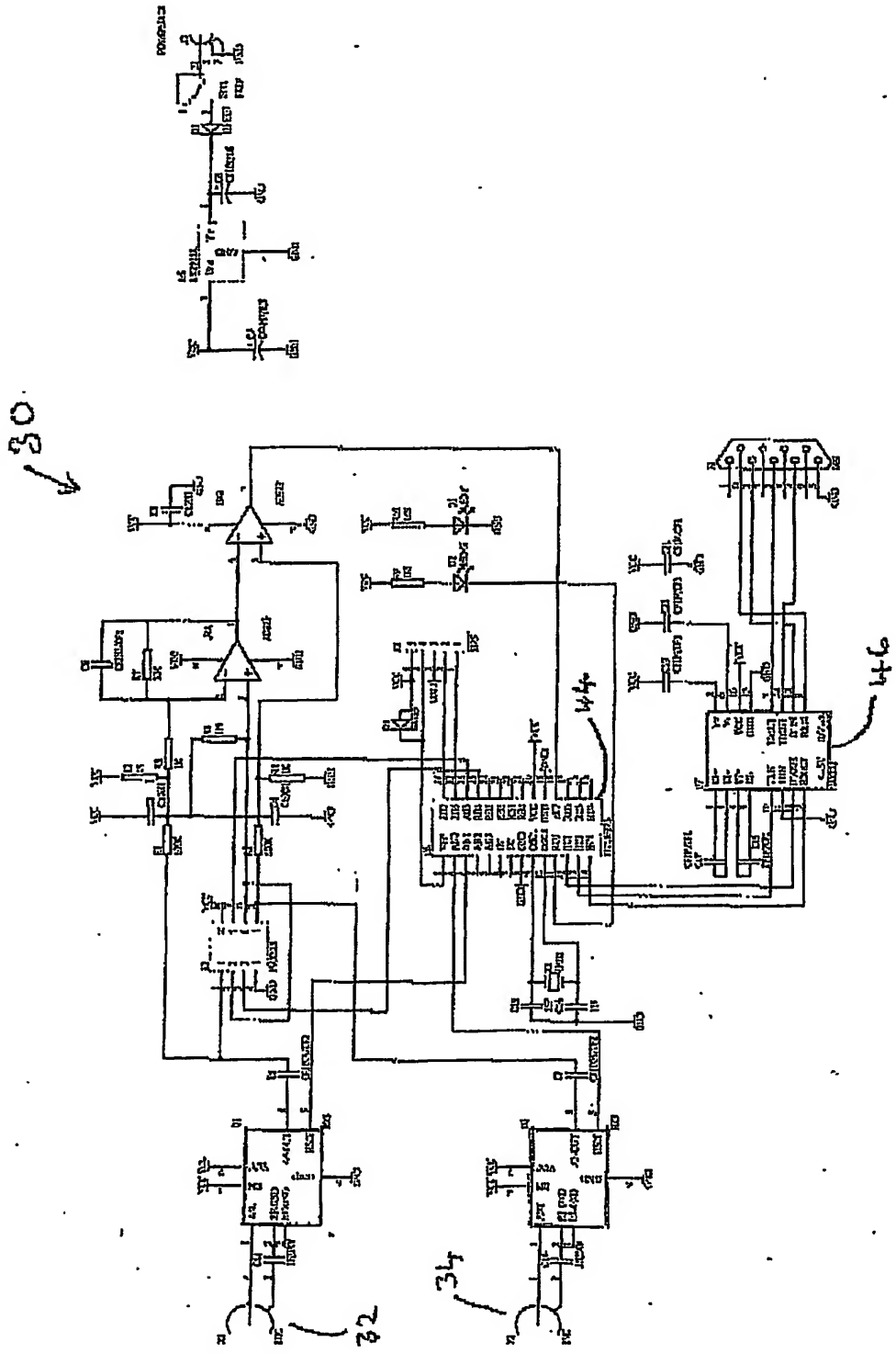

FIGURE 4

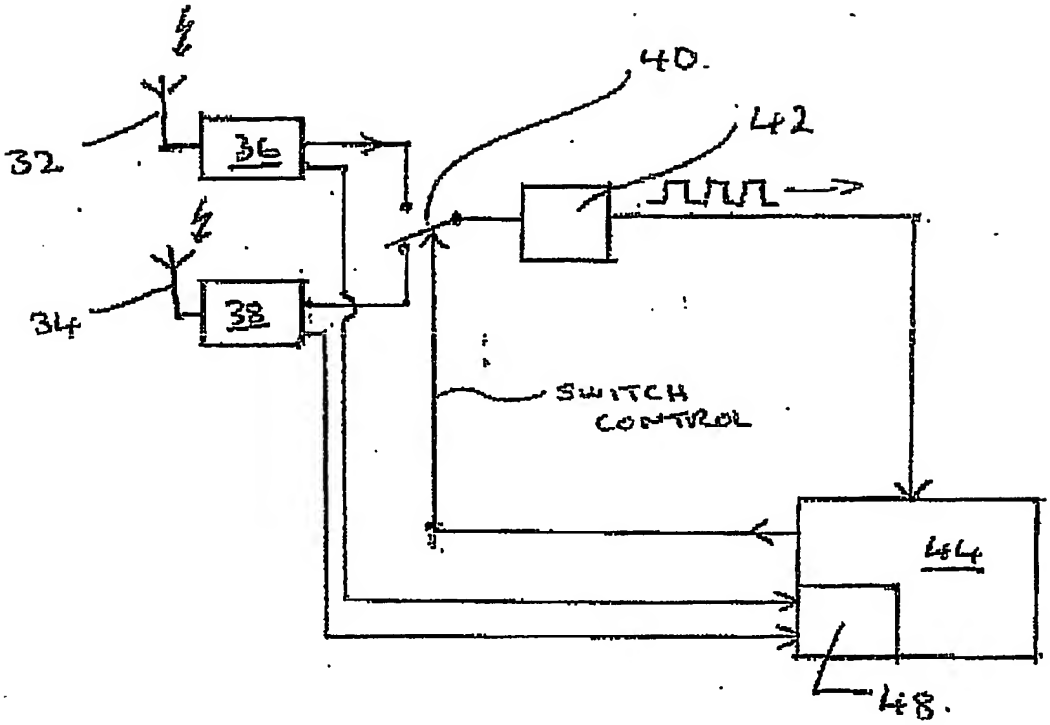

FIGURE 5

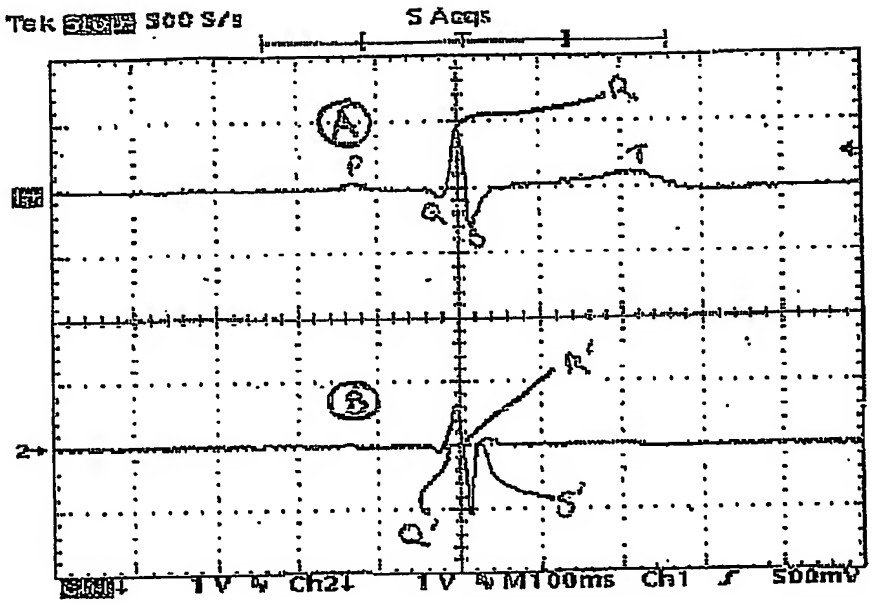

FIGURE 6

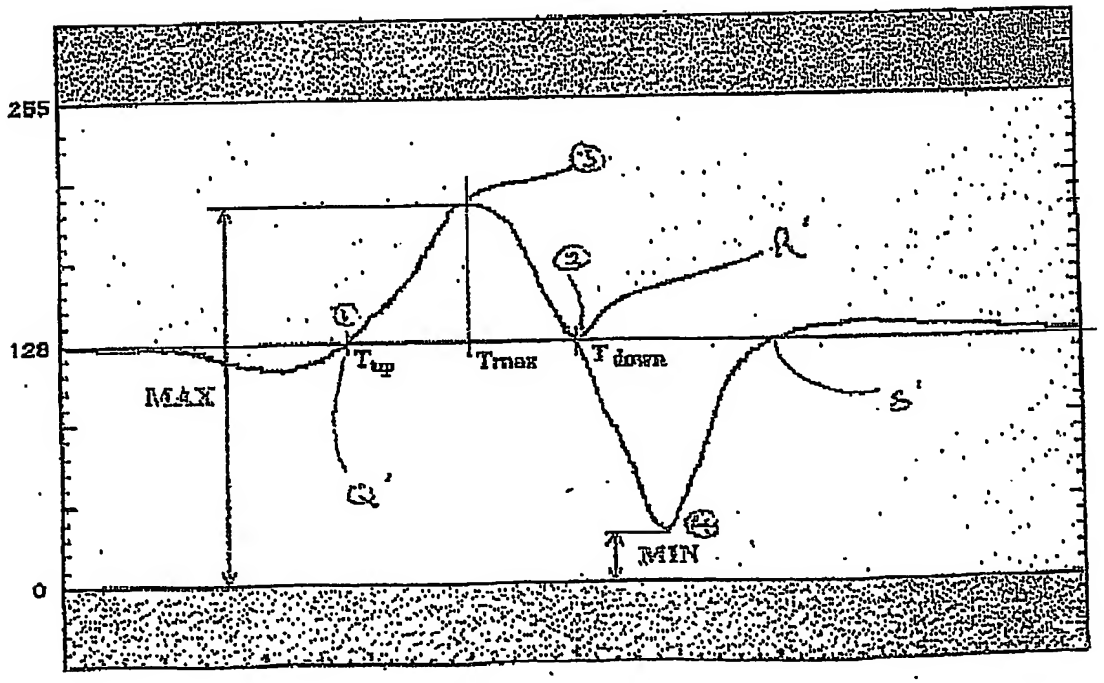

FIGURE 7